REMARKS

The office action of June 3, 2009 has been reviewed and its contents carefully noted. Reconsideration of this case, as amended, is respectfully requested.

Rejection under 35 U.S.C. §103

Claim 10 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Rasor et al. (3,943,936) in view of Heller (6,294,281). Applicants respectfully traverse.

The present invention differs from Rasor et al. as follows. The stimulating timing of the present invention can be changed not only by the ventricular activity but also by fulfilling certain conditions of a patient (e.g.; information sent from outside the body of the patient, electrocardiographic information or a combination thereof). The changes in the stimulation timing triggered by detecting these certain conditions of a patient make it possible to stimulate the patient's heart adequately without adjusting the patient's pacemaker. Furthermore, a plurality of ultra miniature pacemakers may be employed to act together by changing their respective stimulation timings. Therefore, a plurality of ultra miniature pacemakers may optimally stimulate a patient heart by transmitting information between a plurality of pacemakers.

With respect to Rasor et al., the pacemaker(s) are inserted by "minor surgery" (col. 2, line 11) or by "transvenous or transarterial insertion into the heart" (col. 1, lines 66-67). The only mention of a catheter is within the context that it is "possible" to *remove* a failed or worn pacemaker *intravenously* by such a device (col. 11, lines 25-26), seemingly as a last resort. This is in stark contrast to the present invention which claims the direct insertion and/or removal of an ultra miniature pacemaker without a chest incision that does not require surgery or intravenous or transarterial insertion as disclosed by Rasor et al.

Additionally, Rasor et al. use the term "biologically energized power source" (col. 2 lines 32-34). However, by this they go on to explain that such a power source is based upon transforming "hemodynamic pressure into electric energy by means of a suitable transducer" (col. 2, lines 49-50). This is clearly very different from using the *chemistry* of bodily fluids to generate electrical energy by means of oxygen reduction, or redox, reactions. Rasor et al. convert

mechanical energy into electrical energy by means of a transducer. This distinction is emphasized by amending the pending claims to point out that the coating on the cathode electrode is an enzymatic material to enhance the redox reactions (page 9, paragraphs 5 and 6 of the English language translation of the specification of the application).

The Examiner submits that "Heller's invention is clearly designed with safety and biocompatibility issues in mind..." (page 8, lines 7-8 of the outstanding Office Action). Applicants contest this point and submit herewith copies of information data sheets on some of the chemical compounds suggested by Heller for use as redox mediators (col. 6, lines 31-59). For example, from these data sheets the following information is highlighted for the convenience of the Examiner:

1) Osmium metal complexes are highly combustible.

   - Osmium tetroxide is highly toxic to animal tissue.

   - Osmium complexes are known to cause a cessation in breathing.

2) Ruthenium metal compounds are highly combustible.

   - Ruthenium oxide compounds are strong irritants.

   - Ruthenium complexes are known to cause breathing cessation.

3) Iron compounds, such as ferrocene, ferrocyanide and ferricyanide are highly toxic.

4) Nile blue is toxic.

5) Indophenol is also toxic.

Heller do disclose that these toxic compounds and complexes are encased in and bound to a polymer coating, but when these pacemakers are used over long periods of time (for example, 10 years is not outside the realm of the potential lives of these pacemakers) polymers are known to lose their structural and chemical integrity, thereby allowing these toxic mediators to leak into the blood stream of the human patient, causing potentially deleterious side effects. It is

respectfully submitted that the introduction of potentially dangerous chemical compounds into the body, whether encapsulated or not, is contrary to the dual objectives of "safety and biocompatibility", as posited by the Examiner.

The Examiner has noted Reichert et al. in the Office Action. Applicants would like to point out that this patent also discloses that even though the anode, especially, may be "completely encased" in a "gel material" (col. 3, lines 40-65), that a "conventional collector" is used to contain undesirable metabolic by products (note also col. 4, lines 3-15). In contrast, Applicants' metabolic reactants may be readily carried away with the blood without risk of toxic side effects. Accordingly, Applicants' have amended the claims to add that a container for holding electrolytes or metabolic products is not necessary (support may be found on page 9, 2d full paragraph of the English language translation).

The combination of Rasor et al. with Heller would produce a pacemaker that converts mechanical energy (hemodynamic pressure) into electrical energy by means of a transducer. Further, the electrodes would contain toxic substances having potentially deleterious side effects, thus requiring the use of a conventional collector to trap these harmful metabolic by products. In contrast, Applicants' device is a non-toxic "open" fuel cell which generates electrical energy by catalytic chemical reactions with metabolites from bodily fluids at the sites of the anode and cathode electrodes. The metabolic reaction products are non-toxic and may be released into the blood stream without fear of negative health consequences. Thus, the reconsideration and withdrawal of the rejection are respectfully requested.

Claims 11-13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Rasor et al. in view of Heller and Fujii et al. (5,411,535). Applicants respectfully traverse.

Fujii et al. is added as a reference in support of the proposition that the function of an implantable pacemaker may be modified upon acquiring diagnostic information from inside the body of the patient ("at least two detecting means for detecting cardio-information"; col. 2, lines 15-16). Applicants' comments with respect to Rasor et al. in view of Heller have been presented hereinabove are will not be repeated for the sake of brevity. However, they are incorporated herein by reference. In light of Applicants' submission that the instant invention is not obvious over the combination of the first two references, Applicants respectfully submit that Fujii et al.

fail to overcome the deficiencies of Rasor et al. in view of Heller. Accordingly, the reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

Applicant believes the claims, as amended, are patentable over the prior art, and that this case is now in condition for allowance of all claims therein. Such action is thus respectfully requested. If the Examiner disagrees, or believes for any other reason that direct contact with Applicants' attorney would advance the prosecution of the case to finality, he is invited to telephone the undersigned at the number given below.

"Recognizing that Internet communications are not secured, I hereby authorize the PTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file."

Respectfully Submitted:
Sunagawa et al.

By: /Gregory M. Hill, Reg. #31369/
Gregory M. Hill, Reg. No. 31,369
Attorney for Applicant

BROWN & MICHAELS, P.C.
400 M&T Bank Building - 118 N. Tioga St.
Ithaca, NY 14850
(607) 256-2000 • (607) 256-3628 (fax)
e-mail: docket@bpmlegal.com
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